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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,677	04/02/2004	Kinh-Luan (Lenny) Dao	03-302	9708

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
11/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,677	DAO ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,10-13,15,17-21 and 23-46* is/are pending in the application.

4a) Of the above claim(s) *2-4,12,13,15,20,21,24,25,27-30,33-38,44 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,10,11,17-19,23,26,31,32,39-43 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request for RCE, both filed 08/10/2009.

Claims 1-5, 10-13, 15, 17-21, 23-46 are pending.

Claims 2-4, 12, 13, 15, 20, 21, 24, 25, 27-30, 33-38 are drawn to nonelected invention. Election was made with traverse in the reply filed on 12/03/2007.

Claims 44 and 45 were withdrawn from consideration in the office action mailed 04/09/2009 as being directed to non-elected invention by original presentation.

Claims 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 39-43, 46 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action

has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/10/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 39-43, and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing because claim 1 recites that the therapeutic agent is neither partially nor fully embedded within the microparticles, and further recites that the microparticles create pockets which are occupied by the therapeutic agent and from which the therapeutic agent is released. Do the microparticles contain therapeutic agent in their pockets, i.e. therapeutic agent are embedded into the microparticles? Additionally, it is not clear as applicants' intention that the therapeutic agent recited by component (b) of claim 1 is the same therapeutic agent recited by component (c) of the claim. In the later case, does the medical article contain two therapeutic agents?

Claim 17 is confusing because the claim recites that the therapeutic agent and microparticles are admixed together, while claim 1 requires the therapeutic agent is present in the pockets created by the microparticles and not mixed or embedded into the microparticles.

4. The terms "at least", “partially” and “fully” in claim 1 are relative terms which render the claim indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Terms do not set forth the metes and bounds of the claims. Recourse to the specification does not define the terms.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 5, 10, 11, 17-19, 23, 26, 31, 32, 39-43, 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harish et al. (WO 02/26162, currently listed on PTO 892, and copy is provided) in view of any of Mathiowitz et al. (WO 95/24929, currently listed on PTO 892, and copy is provided), Ragheb et al. (US 5,824,049, currently listed on PTO 892) or Su et al. (US 6,844,024, currently listed on PTO 892).

Applicant Claims

Currently amended claim 1 is directed to medical article comprising:

(a) an adhesive region comprising an adhesive;

(b) a therapeutic agent, wherein at least a portion of said therapeutic agent is adhered to a surface of said adhesive region; and

(c) microparticles, at least a portion of which are attached to said surface of said adhesive region, wherein said therapeutic agent is neither partially nor fully embedded within the microparticles and wherein the microparticles create pockets which are occupied by the therapeutic agent and from which the therapeutic agent is released.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Harish teaches implantable device such as a stent coated on preselected regions/portions of its outer surface with therapeutic agent (abstract; claims 3 and 18). The therapeutic agents are deposited on the surface of the stent in the form of dry particles (page 3, 2nd and 3rd full paragraphs; claims 7 and 8). The stent is covered by polymeric primer prior to applying the therapeutic particles to adhere the particle to the surface of the stent, i.e. adhesive (page 4, 1st full paragraph; page 13, 3rd full paragraph; page 16, 1st full paragraph). Therapeutic agents can be protein which is a macromolecule or biostable polymers (page 3, 4th full paragraph; page 8, 1st full paragraph; page 10, last paragraph; page 11, 1st full paragraph). The particles are spherical having diameter from about 5 to 20 microns (page 8, 3rd and 4th full paragraphs). The layer containing the particles is covered by polymeric topcoat that helps immobilization of the particle on the stent surface and the control the release of the therapeutic agents (page 17, 1st paragraph).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Although Harish teaches therapeutic particles coated as dry powder on a stent by virtue of adhesive, however, the reference does not explicitly teach the therapeutic agent occupies the pocket of microparticles as claimed by claim 1.

Mathiowitz teaches microcapsules that contain therapeutic agents stored in its core and surrounded with polymeric shell, such microcapsules can form coating on a stent and results in favorable release of the therapeutic agent such as nucleic acid (abstract; page 6, lines 1-3; page 9, lines 29-31; claim 1-3, 21, 22, 25, 26).

Ragheb teaches stent with therapeutic agents deposited on its outer surface (abstract; col.3, lines 10-11, 34-36; col.5, lines 13-17). The therapeutic agents can be in the form of particles that can be microcapsules having the therapeutic agent adsorbed onto or absorbed into the microcapsules and wherein the particle sizes can affect the release rate of the therapeutic agents (col.18, lines 4-23).

Su teaches stent coated with therapeutic agent on its surface wherein the therapeutic agent is encapsulated into microspheres to stabilize the therapeutic agent and produce burst release when the wall degrades (abstract; col.2, lines 19-20; col.4, lines 1-5; col.5, lines 28-36)

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide stent coated with dry powdered particles of therapeutic agents adhered to the surface of the stent as taught by Harish, and replace the particle with microcapsules/microspheres containing the therapeutic agent as taught by any of Mathiowitz, Ragheb or Su. One would have been motivated to do so because Mathiowitz teaches that microcapsules containing the therapeutic agent control the

release of the therapeutic agent, and because Ragheb teaches that microcapsules having therapeutic agents adsorbed onto or absorbed into the microcapsules provide controlled release of the therapeutic agent or because Su teaches microspheres stabilize the therapeutic agent and produce burst release when the wall degrades. One would reasonably expect formulating stent coated with microcapsules/microspheres containing therapeutic agents adhered to the surface of the stent wherein the therapeutic agent is controllably released to provide the required effect to the patient in need thereof.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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